

A. Package Insert/ Instructions Leaflet

1. Full Insert

2. Panel 1

Read this before using the FC2 Female Condom.

The FC2 Female Condom is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs).

If you are being treated for a sexually transmitted infection (STI) or think you have one, see your healthcare provider.

Important things to note for the best protection with the FC2 Female Condom.

1. Before you try the FC2 be sure to read the directions and learn how to use it correctly.
2. Practice putting the FC2 in the vagina without having sex to get familiar with how it works.
3. Make sure the FC2 is in place before the penis enters.
4. No studies have been conducted to demonstrate if a spermicide is compatible with FC2 material or if using a spermicide increases the FC2's effectiveness.
5. Store the FC2 at normal room temperature.
6. The following are problems that have been reported when using the FC2 during sex:
 - the penis can push the FC2 condom (including outer ring) inside the vagina;
 - the penis slips to the side of the FC2 during intercourse and enters the vagina without FC2 protection;
 - the FC2 female condom breaks during use; and
 - the FC2 slips completely out of the vagina.

In each of the scenarios described above, the risk of vaginal exposure to semen is increased. If any of these occur, you should dispose of that female condom and use a new one.

3. Panel 2

ABOUT THE FC's EFFECTIVENESS

The effectiveness of the FC2 Female Condom is based on a study conducted in South Africa comparing the FC2 Female Condom to the earlier version FC1 Female Condom¹. This comparative study evaluated the FC2 and FC1 with respect to the four possible problems described earlier in the labeling:

- The female condom may break during use;
- The female condom may slip out of the vagina during use;
- The penis may push the female condom into the vagina; and
- The penis may push past the condom into the vagina (unprotected).

These four problems are the only ways that the vagina would be exposed to semen when using the FC2 Female Condom and this comparative study showed that the rates of these problems with the FC1 and FC2 female condoms are similar. Although the FC2 was not studied for contraception or STI protection, the FC2 effectiveness can be inferred on the basis of this comparative study and an earlier study that demonstrated the effectiveness of the FC1 for contraception. These results are given in the table below.

¹ Reference: M. Beksinska et al. Performance of the Reality polyurethane female condom and a synthetic latex prototype: a random crossover trial among South African women. *Contraception*. 2006 Apr; 73(4):386-93.

Below is information on how well different contraceptives protect you against pregnancy. The numbers are based upon typical use and perfect use. Typical use rates indicate that the method may have been used incorrectly, may have not been used with every sex act, or may have failed during use. Perfect use rates indicate that the method was used correctly with every sex act but failed anyway.

Contraceptive Method	% of Women Experiencing an Unintended Pregnancy within the First Year of Use	
	Typical Use	Perfect Use
No method	85	85
Spermicides	29	18
Withdrawal	27	4
Fertility awareness-based methods	25	
Barrier Methods		
Cervical Cap		
No previous births	16	9
Previous births	32	20
Diaphragm + Spermicide	16	6
Condom		
FC1 Female Condom	21	5
Male Condom	15	2
Hormonal Methods		
Combined pill and progestin-only pill	8	0.3
Evra Patch®	8	0.3
NuvaRing®	8	0.3
Depo-Provera®	3	0.3
Implanon®	0.05	0.05
IUD		

ParaGard® (copper T)	0.8	0.6
Mirena® (LNG-IUS)	0.2	0.2
Sterilization		
Female Sterilization	0.5	0.5
Male Sterilization	0.15	0.10

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.

Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception.

Source: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition*. New York NY: Ardent Media, 2007; www.contraceptivetechnology.org

4. Panel 3

HOW TO USE THE FC2 FEMALE CONDOM

1. TO OPEN THE PACKET

- Locate the the arrow at tear notch on the upper right-hand corner and tear open (Fig. A).

Fig. A



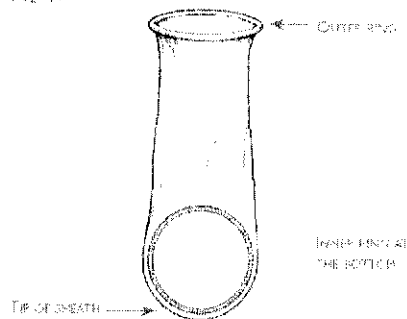
PACKET WRITING - FC2 FEMALE CONDOM

- Rub the outside of the pouch together to be sure the lubrication is evenly spread inside the pouch from the bottom to the top.
- Take out the FC2 and look at it closely to make sure it is not damaged.

2. TO INSERT THE FC2 FEMALE CONDOM

- Find a comfortable position. Try standing with one foot up on a chair, or sit with knees apart, or squat down.
- Be sure the inner ring is at the bottom, closed-end of the pouch (Fig. B).

Fig. B

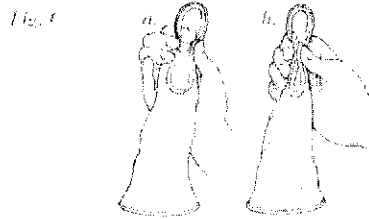


5. Panel 4

HOW TO USE THE FC2 FEMALE CONDOM

3.

- Hold the pouch with the open end hanging down. While holding the outside of the pouch, squeeze the inner ring with your thumb and middle finger.
- Place your index finger between the thumb and middle finger and keep squeezing the inner ring (Fig. C (a)).
- Or just squeeze - whichever is easier for you (Fig. C(b)).



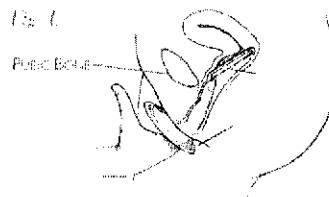
- Still squeezing the FC2 Female Condom with your other hand, spread the lips of the vagina as if you were getting ready to insert a tampon.
- Insert the squeezed FC2 Female Condom as shown in Fig. D.



Take your time. If the FC2 Female Condom is slippery to insert, let it go and start over.

4.

- Now push the inner ring and the pouch the rest of the way up into the vagina with your index finger. Check to be sure the inner ring is up just past your pubic bone (Fig. E).



- You will feel your pubic bone by curving your index finger when it is a couple of inches inside the vagina.

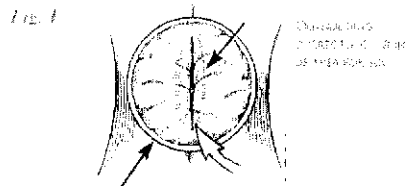
6. Panel 5

HOW TO USE THE FC2 FEMALE CONDOM

This step may be hard to do on the first or second try because the FC2 Female Condom is lubricated.

Take your time and push the closed end of the FC2 Female Condom up to where you can feel the pubic bone.

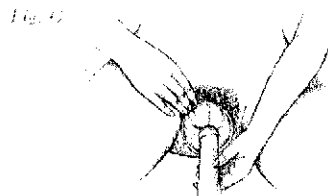
- Make sure the FC2 Female Condom is inserted straight (not twisted) into the vagina.
- It is also important that the outside ring lies against the outer lips of the vagina as shown in Fig.F.



- About one inch of the open end will stay outside your body. FIG. F. While this may look unusual, this part of the FC2 Female Condom helps protect you and your partner during sex. Once the penis enters, the vagina will expand and the slack will decrease.

5.

- Until you and your partner become comfortable using the FC2 Female Condom, use your hand to guide the penis into the vagina. See Fig. G.

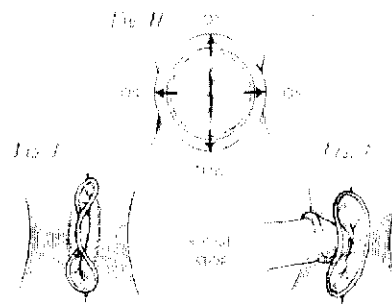


- After two or three times, you should become familiar with using the FC2 Female Condom and should hardly notice the pouch or the outer ring during sex.

6.

During Intercourse

- You may notice that the FC2 Female Condom moves around during sex. See Fig. H.



- Movement side-to-side of the outer ring is normal.
- Sometimes the FC2 Female Condom may slip up and down in the vagina, “riding” on the penis. Both the vagina and the penis are still covered.

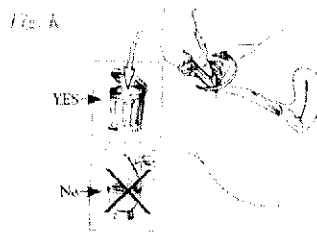
7. Panel 6

HOW TO USE THE FC2 FEMALE CONDOM

- However, if you notice the FC2 Female Condom is slipping out of the vagina, STOP, remove, and insert a new FC2 Female Condom.
- If you begin to feel the outer ring being pushed into the vagina, STOP (Fig. I). Or, if the penis starts to enter underneath or beside the pouch, STOP (Fig. J). Take out the FC2 Female Condom. Put in a new FC2 Female Condom. Make sure the outside part lies over vagina.

7. After Intercourse

To take out the FC2 Female Condom, squeeze and twist the outer ring to keep the sperm inside the pouch. Pull out gently. Throw away in a trash can. Do not flush. Do not reuse. Please see Fig. K.



Remember

To help reduce your risk of pregnancy and the spreading of a sexually transmitted infection:

- Use a new FC2 Female Condom correctly every time you have sex.
- Follow the directions carefully.
- Be sure you don't tear the FC2 with fingernails or other sharp objects.

8. Panel 7

Important Information:

- Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including HIV/AIDS, if used correctly.
- If you are not going to use a male natural rubber latex condom, you can use the FC2 Female Condom to help protect yourself and your partner.
- The FC2 Female Condom only works when you use it. Use it correctly every time you have sex.
- Before you try the FC2 Female Condom, be sure to read the directions and learn how to use it correctly.

RISKS OF USING THE FC2

- Use the FC2 Female Condom correctly every time you have sex. If the FC2 is not used correctly every time, your risk of getting a sexually transmitted infection or becoming pregnant will be higher.
- Incorrect use may result in the FC2 not providing protection. To avoid risk of incorrect use, read the instructions carefully prior to use.
- Research has shown that the following events are rare but can occur when using the FC2:
 - discomfort during insertion
 - pain after insertion, before sex
 - discomfort during sex
 - burning sensation, rash or itching

BENEFITS OF USING THE FC2

- Using the FC2 during sexual intercourse can help protect against getting a sexually transmitted infection or getting pregnant.
- The FC2 does not contain natural rubber latex.
- The FC2 provides women with an option for protection which they can initiate.
- Women can insert the FC2 ahead of the sex act. This allows for a more spontaneous act because an erection is not needed to insert the FC2.

9. Panel 8

Questions you may have about the correct use of the FC2 Female Condom

Q. Will the FC2 Female Condom always protect against pregnancy and STIs?

A. No method is 100 percent effective. Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including AIDS (HIV infection), if used correctly. If you are not going to use a male condom, you can use the FC2 to help protect yourself and your partner.

Q. How do I know when the FC2 Female Condom is up far enough?

A. Using your index finger, push the device so that the lower ring of the device is against the pubic bone. You will find the pubic bone by curving your index finger when it is a couple of inches inside the vagina.

Q. What do I do if the outer ring is pushed inside the vagina?

A. STOP. Remove the FC2 Female Condom device. Insert a new FC2 Female Condom according to the directions.

Q. Will I feel the FC2 Female Condom once it is in place?

A. Yes, it is possible that you will be aware of it.

10. Panel 9

Q. What do I do if the penis is inserted outside the female condom?

A. You should ask your partner to withdraw the penis and help him reinsert the penis inside the condom.

Q. Will the FC2 Female Condom rip or tear while I am using it?

A. Studies show that the FC2 Female Condom rips or tears less than 1% of the time. If you think the FC2 Female Condom has been ripped or torn, remove it right away, throw it away, and insert a new FC2 Female Condom.

Q. Will the FC2 Female Condom bunch up inside the vagina?

A. The FC2 Female Condom should not bunch up inside if it is inserted correctly. If you feel the outer ring begin to slip inside, STOP. Remove the FC2 Female Condom device. Insert a new FC2 Female Condom device according to the directions.

Q. What does the outer ring feel like during sex?

A. While aware of the outer ring, most women say that it does not interfere with intercourse.

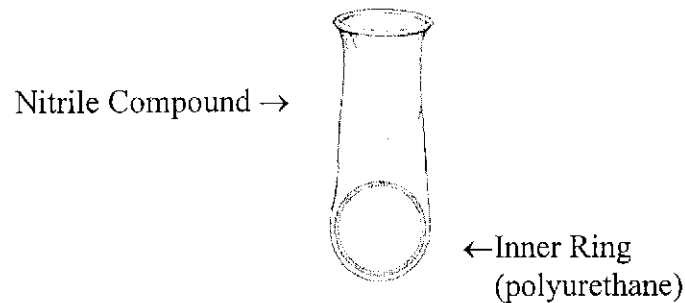
Q. What do I do if the FC2 Female Condom does not stay in place during sex?

A. If the FC2 Female Condom moves down the vagina causing discomfort, either push it back up or remove the FC2 Female Condom. If you remove the FC2 Female Condom, use a new one.

11. Panel 10

Description

The FC2 Female Condom is a soft, loose-fitting sheath. It has a ring at each end. The inner ring at the closed end is made of polyurethane and is used to help insert the FC2 Female Condom inside the vagina and helps to hold it in place. It is not connected to the female condom. The outer rim of the sheath, on the open end stays outside the vagina. The FC2 Female Condom comes prelubricated with silicone.



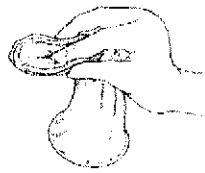
Using the FC2

- The FC2 Female Condom is inserted before sex. Most women insert the FC2 Female Condom between 2 to 20 minutes before sex.
- The FC2 Female Condom should be removed after sex and before you stand up. It is for one-time use.

Some Features of Using the FC2 Female Condom

- You can insert the FC2 Female Condom yourself. It gives you a way to protect yourself.
- The FC2 Female Condom warms up as soon as you insert it. It is both strong and soft.

12. **Panel 11**



Do You Have a Question on How to Use the FC2 Female Condom?
Call your healthcare provider or call 1-800-274-6601.

Manufactured by:
The Female Health Company
Chicago IL / London UK / Malaysia

515 North State Street
Suite 2225
Chicago, IL 60654

www.femalehealth.com

This product protected by
U.S. Patent xxxxxxxxx & others.

Date: _____

13. Panel 12

This leaflet explains how to use the FC2 Female Condom and answers some questions women often ask about its use.

Please read this leaflet carefully before you use the FC2 Female Condom for the first time.

FC2
Female Condom

The FC2 Female Condom is indicated for preventing pregnancy, HIV/AIDS, and other sexually transmitted infections (STIs).